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| 20305. OSJ IS2008 MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE | | | EXAMINER | |
| | | | NOLAN, JASON MICHAEL | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/534,919 SINGH ET AL. Office Action Summary Examiner Art Unit JASON M. NOLAN 1626 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 14 April 2006. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) _____ is/are rejected 7) Claim(s) is/are objected to. 8) Claim(s) 1-20 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.

6) Other:

5) Notice of Informal Patent Application

Page 2

Application/Control Number: 10/534,919

Art Unit: 1626

DETAILED ACTION

This Office Action is responsive to Applicants Preliminary Amendment, filed 05/10/2005. Claims 1-20 are pending in the instant application; of which, Claims 12 & 15 are currently amended and Claims 18-20 are new.

Election/Restrictions

Restriction is required under 35 U.S.C. § 121 and § 372.

Claims 1-20 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

[&]quot;The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

Application/Control Number: 10/534,919

Art Unit: 1626

(i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or

- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or
- (iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,....

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to numerous and widely divergent variables in the substituents of the instant formula, for example: A, B, X, Y, R₁, R₂, and R₃, a precise listing of inventive groups cannot be made. The following groups are exemplary:

- Group I: Claims 1, 2, & 11, drawn to compounds and compositions according to the instant formula wherein Y = S, S(O)₂, or S(O) and A is aryl.
- Group II: Claims 1-11, drawn to compounds and compositions according to the instant formula wherein Y = S, S(O)₂, or S(O) and A is heteroaryl.
- Group III: Claims 1, 2, & 11, drawn to compounds and compositions according to the instant formula wherein Y = O and A is aryl.
- Group IV: Claims 1, 2, & 11, drawn to compounds and compositions according to the instant formula wherein Y = O and A is heteroaryl.

Application/Control Number: 10/534,919

Art Unit: 1626

Group V: Claims 1, 2, & 11, drawn to compounds and compositions according to the instant formula wherein $Y = C(R_4)(R_5)$ and A is aryl.

Group VI: Claims 1, 2, & 11, drawn to compounds and compositions according to the instant formula wherein $Y = C(R_4)(R_5)$ and A is heteroaryl.

Group VII: Claims 1, 2, & 11, drawn to compounds and compositions according to the instant formula wherein $Y = NR_4$, $NC(O)(R_4)$, $NSO_2(R_4)$ and A is arvl.

Group VIII: Claims 1, 2, & 11, drawn to compounds and compositions according to the instant formula wherein $Y = NR_4$, $NC(O)(R_4)$, $NSO_2(R_4)$ and A is heteroarvl.

Group IX: Claims 12-20, drawn to methods of using the compositions of the instant formula

The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 C.F.R. § 1.475(a) **Group I - Group IX** lack unity of invention since, under 37 CFR § 1.475:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Application/Control Number: 10/534,919

Art Unit: 1626

The structural moiety common to **Group I – Group IX** is lacking because the core of the hetero-ring shown in the instant formula may contain multiple, distinct atoms for **Y**. Further, the substituent **B** may be a variety of distinct aryl or heteroaryl moieties.

However, even if the structural moiety common to **Group I – Group IX** is considered to include the variables **B** and **Y**, the structural moiety common to **Group I – Group IX** is not a special technical feature because it fails to define a contribution over the prior art. For instance, the reference presented in the IDS authored by Sing *et al.* (*Bioorganic & Medicinal Chemistry.* **2001**, *11*, 91-94) has compounds according to the formula of the instant invention, i.e. compound **2c** in Table I (p. 92), wherein $R_1 = C_1$ -alkyl-C(O)OR₆; $R_6 = H$; X = S; Y = S; Y

Therefore, Claims 1-20 are not so linked as to form a single general inventive concept and there is a lack of unity of invention. The variables vary extensively and when taken as a whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on the search and examination of the claimed subject matter.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a product or a method of use.

Furthermore, with respect to **Group I – Group IX**, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application Application/Control Number: 10/534,919 Page 6

Art Unit: 1626

containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product: or
- (4) A process and an apparatus or means specially designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Moreover, according to 37 CFR 1.475(c).

If an application contains claims to more or less that one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than a product and a method of use, and according to 37 CFR 1.475(e),

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

As a result, the claims lack unity of invention and applicant is required to elect a single invention.

Application/Control Number: 10/534,919 Page 7

Art Unit: 1626

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason M. Nolan, Ph.D. whose telephone number is (571) 272-4356 and electronic mail is Jason.Nolan@uspto.gov. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jason M. Nolan, Ph.D./

Examiner, Art Unit 1626

/Rebecca L Anderson/

Primary Examiner, Art Unit 1626

Art Unit: 1626